REMARKS

Status of Claims:

Claims 38-39, 42, 44-51, 56-63, 67-70, 72-75, 78-80, 83-84, 86-92, 94-100, 102-105, 107-108, 110-116, 118-119, 121-123, and 126-141 were pending in the application. Claims 47, 59, 61, 89, 97, and 99 are hereby cancelled without prejudice or disclaimer of subject matter contained therein. The Applicants reserve the right to prosecute the subject matter thereof in one or more divisional, continuation, and continuation-in-part application(s). Each of the pending claims defines an invention that is novel and unobvious over the cited art. Favorable re-consideration and allowance of the present application based on the above-described amendments and the following remarks are respectfully requested.

The applicant does not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserves the right to pursue such subject matter in continuing and/or divisional applications.

Rejection Under 35 U.S.C. § 112(2nd):

Claims 38-39, 42, 44-51, 56-63, 67-70, 72-75, 78-80, 83-84, 86-92, 94-100, 102-105, 107-108, 110-116, 118-119, 121-123, and 126-141 were rejected under 35 U.S.C. 112(2nd) as indefinite. The Examiner alleges that the recited methods are incomplete as missing essential steps. The Examiner alleges: 1) there is no recitation of a patient population; and, 2) the claims fails to define a period of time during which treatment occurs.

In response to the present rejection, the Applicants amend the independent claims (38, 51, 61, 83, 92, 99, and 115) to recite a patient population, *i.e.*, "a female human selected for controlled ovarian stimulation" and to recite a treatment period, *i.e.*, "wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle."

These recitations are supported by original disclosure. The patient population is disclosed at page 1, lines 13-15. The treatment period is disclosed at page 3, lines 26-29. In

view of the original disclosures, these recitations do not comprise new matter.

Rejection Under 35 U.S.C. § 112(2nd):

Claims 38-39, 42, 44-51, 56-63, 67-70, 72-75, and 78-80 were rejected under 35 U.S.C. 112(2nd) as indefinite. The Examiner alleges that the actual dosage regime is not clear.

The Applicants amend the independent claims (38, 51, and 61) to recite "wherein the LHRH antagonist is administered as one or two, daily, 3mg doses, beginning on menstrual cycle day 1 and continuing through day 10." The added recitation does not comprise new matter in view of original disclosure at page 4, lines 13-14 and 28-30.

Rejection Under 35 U.S.C. § 112(2nd):

Claims 38-39, 42, 44-51, 56-60 were rejected under 35 U.S.C. 112(2nd) as indefinite. The Examiner alleges that the dosages of LH and FSH are unclear in view of the recitation "wherein the dose…remains the same…"

The applicants cancel the accused recitation from the claims. Moreover, the claims have been amended to recite a single FSH dose.

The recitation "single or second" is cancelled from Claims 46 and 132.

Rejection Under 35 U.S.C. § 112(2nd):

Claims 61-63, 65, 67-70, 72-75, 78-80, 99-100, 102-105, 107-108, and 110-114 were rejected under 35 U.S.C. 112(2nd) as indefinite. The Examiner alleges that the recitation "without administration of a hormone or hormone agonist to induce ovulation" renders the claims indefinite.

The Applicants hereby cancel Claims 47, 59, 89, and 97 without prejudice, admission, or disclaimer of subject matter. The Applicants hereby cancel the accused recitation from independent Claims 61 and 99.

Rejection Under 35 U.S.C. § 112(2nd):

Claims 83-84 and 86-91 were rejected under 35 U.S.C. 112(2nd) as indefinite. The Examiner alleges that the recitation "for multiple days" renders the claims indefinite where ovulation occurs only one day after LHRH antagonist administration.

The Applicants amend Claim 83 to recite "until ovulation."

Rejection Under 35 U.S.C. § 112(1st), New Matter:

Claims 47, 59, 61-63, 65, 67-70, 72-75, 78-80, 97, 99-100, 102-105, 107-108, 110-114, and 121 were rejected under 35 U.S.C. 112(1st) as failing to comply with the written description requirement. The Examiner alleges that the negative recitation "without administration of a hormone or hormone agonist to induce ovulation" is not supported in the specification.

The Applicants hereby cancel Claims 47, 59, 89, and 97 without prejudice, admission, or disclaimer of subject matter. The Applicants hereby cancel the accused recitation from independent Claims 61 and 99.

Rejection Under 35 U.S.C. § 102(b): Diedrich.

Claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich *et al.* (Hum Reprod. 1994). The examiner alleges that Diedrich *et al.* describe a method for obtaining the production of a fertilizable oocyte within a program of COS/ART comprising (a) administering HMG to induce follicle growth, and (b) administering cetrorelix in a dosage regimen of multiple daily doses of 3 mg/day to prevent a premature LH surge, wherein the first daily dose of cetrorelix was administered on day 7 of the cycle, and daily treatment continued until ovulation was induced by administration of HCG.

The Applicants amend independent Claims 38, 51, 61, 83, 92, and 99 to recite the administration of a single HMG dose (a single FSH dose and a single LH dose) per dosage regime. The applicants respectfully submit that the claims of the present application, as clarified by the present amendment, are directed to a method that is different from and is not anticipated by the method described by Diedrich *et al.*

The present invention relates to a program of COS/ART comprising the administration of a single HMG dose to induce follicle growth. In contrast, Diedrich discloses daily HMG administration. Moreover, the dosage of Diedrich is recalculated after five days. Thus, the present invention, as clarified by the present amendment, distinguishes over Diedrich.

Rejection Under 35 U.S.C. § 102(b): Olivennes.

Claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 are rejected under 35 U.S.C. 102(a) as being anticipated by Olivennes *et al.*, "Scheduled administration of a gonadotrophin-releasing hormone antagonist (Cetrorelix) on day 8 of in-vitro fertilization cycles: a pilot study," Human Reprod., 10:1382-86 (1995).

The present application claims the priority of U.S. Provisional Application 60/011,282, filed February 7, 1996. Olivennes was accepted for publication on April 10, 1995 which date is less than a year prior to the present priority date. Olivennes could not have been made available to the public for some time after its acceptance for publication. Thus, Olivennes is not available as prior art under 35 U.S.C. § 102(b).

In view of the foregoing, withdrawal of the rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35 U.S.C. §102(b) as allegedly being anticipated by Olivennes *et al.* is respectfully requested.

Obviousness-Type Double Patenting Rejection

Claims 38-39, 42, 45-51, 56-62, 65, 67-74, 78-82, 86-92, 94-100, 102-105, 107-108, 110-116, 118-119, 121-123, 126-128 and 129-141 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 26-42 of co-pending U.S. Patent Application No. 10/661,780, now U.S. 7,393,834. The claims of Application No. 10/661,780 are directed to a method of treating infertility disorders that comprises inducing follicle growth by administration of hMG or recombinant FSH in combination with clomiphene, which method is considered to be encompassed by the claims of the present application.

The applicants submit a terminal disclaimer over U.S. 7,393,834.

CONCLUSION

Accordingly, it is respectfully requested that the foregoing amendments be entered, that the application as so amended receive an examination on the merits, and that the claims as now presented receive an early allowance.

In the event the examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

The Commissioner is hereby authorized to charge any fees or credit any overpayment associated with this communication, including any extension fees or fees for the net addition of claims, to Deposit Account No. 033975, Order No. 098501-0235299.

Respectfully submitted,

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